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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,422	09/08/2006	Boris Schwartsburd	057878-000024	8394

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1656	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,422	SCHWARTSBURD ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 42-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 42-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of IL-18BP as the protein of interest in the response to restriction requirement filed January 15, 2008 is acknowledged. Upon reconsideration, the proteins of IL6-IL6R and beta-galactosidase will be included for examination. Therefore, claims 1-20 and 42-45, and IL-18BP, IL6-IL6R and beta-galactosidase as the protein of interest are examined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-20 and 42-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-20 and 42-45 are directed to a method of purifying or capturing a non-immunoglobulin protein of interest having between one and ten immunoglobulin-like (Ig-like) domains from a biological fluid, comprising the steps of: contacting the biological fluid containing the protein of interest with an Hydrophobic Charge Induction Chromatography (HCIC) resin, washing out the resin to remove unbound contaminants, and eluting the protein of

interest by treating the resin with a solution having an acidic pH or with a solution comprising an organic solvent; and to specific proteins of interest.

In *University of California v. Eli Lilly & Co.*, 43 USPQ2d 1938, the Court of Appeals for the Federal Circuit has held that "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials". As indicated in MPEP § 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that Applicant was in possession of the claimed genus. In addition, MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. 3

While the specification describes the use of specific HCIC resin such as MEP-HyperCel and propylene glycol as the organic solvent at a concentration between 25 and 50% in the method of purifying specific non-immunoglobulin proteins having between one and ten immunoglobulin-like (Ig-like) domains (pages 5-7), the specification does not disclose a genus of variants for HCIC resins and organic solvents used in the claimed method. Furthermore, the specification has not identified any other HCIC resins and organic solvents used in the claimed

method, nor has described the effects of using the variants. A single species of HCIC resin such as MEP-HyperCel and a single species of organic solvent such as propylene glycol used in the claimed method (Examples 1-4, 8 and 9) do not provide sufficient written description for the genus of variants for HCIC resins or organic solvents, when there is substantial variation in the whole genus. The lack of description of using various HCIC resins and organic solvents in the claimed method, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-20 and 42-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1-20 and 42-45 are indefinite because of the use of the term "Hydrophobic Charge Chromatography (HCIC) resin". The term cited renders the claim indefinite, it is not clear how "Hydrophobic Charge Chromatography" is correlated to HCIC. It appears the term "Hydrophobic Charge Induction Chromatography" is used (see page 4, line 28-29 of the specification). Claims 2-20 and 42-45 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

5. Claim 2 recites the limitation "step a)" in line 2. There is insufficient antecedent basis for this limitation in the claim. See also claims 5 and 6.

6. Claim 3 recites the limitation "step c)" in line 2. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 7 recites the limitation "step b)" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 8 is included in the rejection because it is dependent on a rejected claim and does not correct the deficiency of the claim from which it depends.

8. Claim 9 is indefinite because of the use of the term "derived from". The term cited renders the claim indefinite, it is not clear how different the fraction derived from an earlier chromatographic step is from the fraction from an earlier chromatographic step. Use of the term "obtained from" is suggested.

9. Claims 11and 42 are indefinite because of the use of the term "functional derivative". The term cited renders the claim indefinite, it is not clear how different the functional derivative is from the functional protein, and what is the structure of the functional derivative.

10. Claim 16 recites the limitation "about 94 fold" in line 2, which means the purification factor can be equal to, less than or more than 94 fold. There is insufficient antecedent basis for this limitation in the claim because claim 15 recites the purification factor is in the range of 11 and 94 fold, which means the purification factor cannot be more than 94 fold.

11. Claim 18 recites the limitation "about 3.1 fold" in line 2, which means the concentration factor can be equal to, less than or more than 3.1 fold. There is insufficient antecedent basis for this limitation in the claim because claim 17 recites the concentration factor is in the range of 1.5 and 3.1 fold, which means the concentration factor cannot be more than 3.1 fold.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 42-43 are rejected under 35 U.S.C. 102(b) as anticipated by Kim *et al.* (PNAS 97, 1190-1195 (Feb 2000); reference C15 in IDS filed 2/16/06).

Kim *et al.* teach four human and two mouse Il-18 binding proteins (IL-18BP) were expressed and purified on metal affinity columns (pages 1191-1192; Fig. 3; claims 42-43), the IL-18BPs were also assessed for binding and neutralization of IL-18 biological activity (Fig. 2). MPEP 2113 states that "[E]ven though product-by-process claims are limited by and defined the process, determination of patentability is based on the product itself". Since the purified IL-18BP taught by Kim *et al.* is not different from the claimed IL-18BP, thus the reference anticipates the claimed invention.

13. Claims 42 and 45 are rejected under 35 U.S.C. 102(b) as anticipated by Gerdy *et al.* (WO 01/04276; reference B2 in IDS filed 2/16/06).

Gerdy *et al.* teach a cold-active beta-galactosidase from the strain LMG P-19143 is purified from affinity column and the enzyme is 99% pure as determined by SDS-PAGE (pages 11-13; claims 42 and 45). MPEP 2113 states that "[E]ven though product-by-process claims are limited by and defined the process, determination of patentability is based on the product itself". Since the purified beta-galactosidase taught by Gerdy *et al.* is not different from the claimed beta-galactosidase, thus the reference anticipates the claimed invention.

14. Claims 42 and 44 are rejected under 35 U.S.C. 102(b) as anticipated by Revel *et al.* (WO 99/02552).

Revel *et al.* teach IL-6R/IL6 chimera is expressed in CHO cells and purified from affinity column (Example 6; pages 38-39; claims 42 and 44). MPEP 2113 states that "[E]ven though product-by-process claims are limited by and defined the process, determination of patentability is based on the product itself". Since the purified IL-6R/IL6 chimera taught by Revel *et al.* is not different from the claimed IL-6R/IL6 chimera, thus the reference anticipates the claimed invention.

Conclusion

15. No claims are allowed.

Art of Record

Hydrophobic charge induction chromatography (HCIC) has been used to purify chymosin, chymotrypsinogen and lysozyme (Burton *et al.*, J. Chromatography A 814, 71-81 (1998)); botulinum neurotoxin fragments (Weatherly *et al.*, J. Chromatography A 952, 99-110 (2002)); and antibodies (Schwartz *et al.*, J. Chromatography A 908, 251-263 (2001)). However, the HCIC has not been used for purifying a non-immunoglobulin protein having between one and ten immunoglobulin-like (Ig-like) domains.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/
Primary Examiner, Art Unit 1656

CMK
February 26, 2008